

The Mammography Quality Standards Act of 1992 (MQSA) was amended by the Mammography Quality Standards Reauthorization Act of 1998(MQSRA). MQSRA contains text amending MQSA.

A copy of MQSA as amended by MQSRA is available at <http://www.fda.gov/cdrh/mammography/mqsa-act.html> [text] or <http://www.fda.gov/cdrh/mammography/pubs/mqsa-act.pdf> [PDF]

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MAMMOGRAPHY QUALITY STANDARDS REAUTHORIZATION ACT OF 1998  
Public Law 105-248  
105th Congress

An Act

To amend the <<NOTE: Oct. 9, 1998 - [H.R. 4382]>> Public Health Service Act to revise and extend the program for mammography quality standards.

Be it enacted by the Senate and House of Representatives of the United States of America in <<NOTE: Mammography Quality Standards Reauthorization Act of 1998.>> Congress assembled,

SECTION 1. SHORT <<NOTE: 42 USC 201 note.>> TITLE.

This Act may be cited as the ``Mammography Quality Standards Reauthorization Act of 1998''.

SEC. 2. AUTHORIZATION OF APPROPRIATIONS.

(a) In General.--Section 354(r)(2) of the Public Health Service Act (42 U.S.C. 263b(r)(2)) is amended in each of subparagraphs (A) and (B) by striking ``1997'' and inserting ``2002''.

(b) Technical Amendments.--Section 354(r)(2) of the Public Health Service Act (42 U.S.C. 263b(r)(2)) is amended in subparagraph (A) by striking ``subsection (q)'' and inserting ``subsection (p)'', and in subparagraph (B) by striking ``fiscal year'' and inserting ``fiscal years''.

SEC. 3. APPLICATION OF CURRENT VERSION OF APPEAL REGULATIONS.

Section 354(d)(2)(B) of the Public Health Service Act (42 U.S.C. 263b(d)(2)(B)) is amended by striking ``42 C.F.R. 498 and in effect on the date of the enactment of this section'' and inserting ``part 498 of title 42, Code of Federal Regulations''.

SEC. 4. ACCREDITATION STANDARDS.

(a) In General.--Section 354(e)(1)(B) of the Public Health Service Act (42 U.S.C. 263b(e)(1)(B)) is amended--

(1) in clause (i), by striking ``practicing physicians'' each place such term appears and inserting ``review physicians''; and (2) in clause (ii), by striking ``financial relationship'' and inserting ``relationship''.

(b) Definition.--Section 354(a) of the Public Health Service Act (42 U.S.C. 263b(a)) is amended by adding at the end the following:

“(8) Review physician.--The term ‘review physician’ means a physician as prescribed by the Secretary under subsection (f )(1)(D) who meets such additional requirements as may be established by an accreditation body under subsection (e) and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) on behalf of the accreditation body.”.

#### SEC. 5. CLARIFICATION OF FACILITIES' RESPONSIBILITY TO RETAIN MAMMOGRAM RECORDS.

Section 354(f )(1)(G) of the Public Health Service Act (42 U.S.C. 263b(f )(1)(G)) is amended by striking clause (i) and inserting the following:

“(I) a facility that performs any mammogram--

“(I) except as provided in Subclause (II), maintain the mammogram in the permanent medical records of the patient for a period of not less than 5 years, or not less than 10 years if no subsequent mammograms of such patient are performed at the facility, or longer if mandated by State law; and

“(II) upon the request of or on behalf of the patient, transfer the mammogram to a medical institution, to a physician of the patient, or to the patient directly; and”.

#### SEC. 6. DIRECT REPORTS TO PATIENTS.

Section 354(f )(1)(G)(ii) of the Public Health Service Act (42 U.S.C. 263b(f )(1)(G)(ii)) is amended by striking subclause (IV) and inserting the following:

“(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person; and”.

#### SEC. 7. SCOPE OF INSPECTIONS.

Section 354(g)(1)(A) of the Public Health Service Act (42 U.S.C. 263b(g)(1)(A)) is amended in the first sentence--

(1) by striking “certified”; and

(2) by inserting “the certification requirements under subsection (b) and” after “compliance with”.

#### SEC. 8. DEMONSTRATION PROGRAM REGARDING FREQUENCY OF INSPECTIONS.

Section 354(g) of the Public Health Service Act (42 U.S.C. 263b(g)) is amended--

(1) in paragraph (1)(E), by inserting “, subject to paragraph (6)” before the period; and

(2) by adding at the end the following paragraph:

“(6) Demonstration program.--

“(A) In general.--The Secretary may establish a demonstration program under which inspections under paragraph (1) of selected facilities are conducted less frequently by the Secretary (or as applicable, by State or local agencies acting on behalf of the Secretary) than the interval specified in subparagraph (E) of such paragraph.

“(B) Requirements.--Any demonstration program under subparagraph (A) shall be carried out in accordance with the following:

“(I) The program may not be implemented before April 1, 2001. Preparations for the program may be carried out prior to such date.

“(ii) In carrying out the program, the Secretary may not select a facility for inclusion in the program unless the facility is substantially free of incidents of noncompliance with the standards under subsection (f ). The Secretary may at any time provide that a facility will no longer be included in the program.

“(iii) The number of facilities selected for inclusion in the program shall be sufficient to provide a statistically significant sample, subject to compliance with clause (ii).

“(iv) Facilities that are selected for inclusion in the program shall be inspected at such intervals as the Secretary determines will reasonably ensure that the facilities are maintaining compliance with such standards.”.

## SEC. 9. CLARIFICATION OF AUTHORITY TO DELEGATE INSPECTION RESPONSIBILITY TO LOCAL GOVERNMENT AGENCIES.

Section 354 of the Public Health Service Act (42 U.S.C. 263b) is amended--

(1) in subsections (a)(4), (g)(1), (g)(3), and (g)(4), by inserting “or local” after “State” each place such term appears;

(2) in the heading of subsection (g)(3), by inserting “or local” after “state”; and

(3) in subsection (i)(1)(D)--

(A) by inserting “or local” after “State” the first place such term appears; and

(B) by inserting “or local agency” after “State” the second place such term appears.

## SEC. 10. PATIENT NOTIFICATION CONCERNING HEALTH RISKS.

(a) Requirement.--Section 354(h) of the Public Health Service Act (42 U.S.C. 263b(h))

is amended--

(1) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(2) by inserting after paragraph (1) the following:

“(2) Patient information.--If the Secretary determines that the quality of mammography performed by a facility (whether or not certified pursuant to subsection (c)) was so inconsistent with the quality standards established pursuant to subsection (f ) as to present a significant risk to individual or public health, the Secretary may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Secretary may require.”.

(b) Civil Money Penalty.--Section 354(h)(3) of the Public Health Service Act (42 U.S.C. 263b(h)(3)), as redesignated by subsection (a)(1), is amended--

(1) by striking “and” at the end of subparagraph (B);

(2) by redesignating subparagraph (C) as subparagraph (D); and

(3) by inserting after subparagraph (B) the following:

“(C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and”.

(c) Conforming Amendment.--Section 354(h)(4) of the Public Health Service Act (42 U.S.C. 263b(h)(4)), as redesignated by subsection (a)(1), is amended by striking “paragraphs (1) and (2)” and inserting “paragraphs (1) through (3)”.

## SEC. 11. REQUIREMENT TO COMPLY WITH INFORMATION REQUESTS.

Section 354(i)(1)(C) of the Public Health Service Act (42 U.S.C. 263b(i)(1)(C)) is amended--

(1) by inserting after “Secretary” the first place such term appears the following:

“(or of an accreditation body approved pursuant to subsection (e))”; and

(2) by inserting after “Secretary” the second place such term appears the

following: “(or such accreditation body or State carrying out certification program requirements pursuant to subsection (q))”.

## SEC. 12. ADJUSTMENT TO SEVERITY OF SANCTIONS.

Section 354(i)(2)(A) of the Public Health Service Act (42 U.S.C. 263b(i)(2)(A)) is amended by striking “makes the finding ” and all that follows and inserting the following: “has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that--

“(I) the failure or violation was intentional; or

“(ii) the failure or violation presents a serious risk to human health.”.

SEC. 13. TECHNICAL AMENDMENT.

Section 354(q)(4)(B) of the Public Health Service Act (42 U.S.C. 263b(q)(4)(B)) is amended by striking ``accredited" and inserting ``certified".

Approved October 9, 1998.

LEGISLATIVE HISTORY--H.R. 4382 (S. 537):

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HOUSE REPORTS: No. 105-713 (Comm. on Commerce).

CONGRESSIONAL RECORD, Vol. 144 (1998):

Sept. 15, considered and passed House.

Sept. 25, considered and passed Senate.

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